

South Carolina

AIDS Drug Assistance Program

TECHNICAL ASSISTANCE GUIDELINES

South Carolina
Department of Health and Environmental Control
Division of STD/HIV-Ryan White Services
April 2006

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Overview

The South Carolina AIDS Drug Assistance program (SC ADAP) was established under the Ryan White CARE Act to provide drugs to treat HIV disease and/or to prevent the serious deterioration of health arising from HIV disease in eligible individuals, including measures for the prevention and treatment of opportunistic infections and document the progress made in making the drugs available. The SC ADAP is operated through a centralized pharmacy and an insurance assistance program located at the Department of Health and Environmental Control (DHEC). Currently 56 drugs are on the approved formulary. See appendix for the current list. ADAP currently has over 2900 clients enrolled and serves approximately 1,900 clients a month. The SC ADAP has an advisory body of infectious disease (ID) and other HIV specialty physicians and program staff that meets annually to review the SC ADAP formulary and make recommendations for program improvements.

Mail SC ADAP Central Pharmacy applications, prescriptions, and correspondence to:

Central Pharmacy SP-16
P.O. Box 809
State Park, SC 29147-0809
Phone: 803-896-6250
FAX: 803-896-6252

Mail SC ADAP Insurance applications, invoices, and correspondence to:

Patti Sullivan
3rd Floor, Mills/Jarrett
Box 101106
Columbia, SC 29211
Phone: 803-898-0214

I. Application for Services

Applications to the SC ADAP may come from several sources. Applications may come from Ryan White Title II, III, or IV providers; private physician offices; primary care facilities; or other clinics. Applications are available from the SC ADAP or local consortia, or they are available at the STD/HIV Division website: <http://www.dhec.sc.gov/health/disease/stdhiv/adap.htm>.

The SC ADAP accepts and processes only applications that are filled out completely and accurately. **Applications must include the patient's legal first and last name as well as an accurate social security number and proof of household income.** If the applicant does not have a social security number please write N/A in the space provided for SSN. Incomplete applications will be returned to the case manager or physician for completion. Application forms must be received in writing with original signatures. In emergency situations, with prior approval of the SC ADAP director, a faxed application may be accepted with the original application to follow immediately in the mail. Applications with a print date prior to 04/2006 will not be accepted due to their lack of HIPAA required language authorizing the release of patient information. The application print date can be found in the lower left-hand corner of the first page. Priority for acceptance is given to persons with lower CD4 counts or higher viral loads. If other circumstances warrant expediting, those circumstances must be written in the allocated space on the back of the application.

Time Frames

In general, all applications will be reviewed within 30 days of receipt. Approved applications will usually be activated within 60 to 120 days of receipt. Once a decision is made, patients, physicians, and case managers should receive written or electronic notification within 10-15 working days of final determination of application status. Any changes to the application once submitted, will result in additional processing time.

II. Eligibility Determination

The patient is responsible for providing all proof of social (to include SSN) and financial eligibility for the SC ADAP. The physician is responsible for providing all proof of medical information. Drugs may not be dispensed in any case until eligibility is confirmed medically and financially. A lack of health insurance pharmacy benefits must also be established. One-month certifications or one-day “emergency” certifications are not permissible with SC ADAP funds. If there are extenuating circumstances, please contact the SC ADAP. Otherwise the purchase of drugs will need to be handled by other resources until the SC ADAP application is approved. Other resources may include Ryan White Title II Consortia funding, Title III programs, pharmaceutical company drug assistance programs, or private pay.

A. Residency

The Ryan White CARE Act program is for outpatient, non-institutionalized individuals only. Persons under the care, custody, and/or control of the state or a corrections program are considered institutionalized. Therefore, persons living in prisons and hospitals are not eligible for ongoing services from the SC ADAP. One exception to this policy exists based on July 2001 revisions to the CARE Act. The SC ADAP issued a letter on April 10, 2002 informing the South Carolina Association of Counties that, effective immediately, the SC ADAP will be able to supply medication to pretrial detainees who are currently receiving their HIV medication through the SC ADAP on a regular basis. See Section V. A. for clarification. In order to be eligible for the SC ADAP, applicants and recipients must be living in the state of South Carolina at the time of application. Persons who reside elsewhere are not eligible. Applicants do not have to document citizenship or immigration status in order to be eligible for program services. However, such non-documented applicants must have been living in South Carolina for a minimum of three months (Exceptions to this rule may be made on a case by case basis). Arrangements to allow a South Carolina patient to have a limited supply of medications for an out-of-town trip may also be made on a case-by-case basis.

B. Economic Eligibility Criteria

A patient's household income is one of the primary criteria used to determine eligibility for SC ADAP. Income must be documented in writing in the patient's record. Income of the applicant and his/her spouse is counted in determining financial eligibility, to include:

Salaries	Tips
Wages	Business Profits
Public Assistance	Rents, Interest, Dividends
Sick Pay	Scholarships
Royalties and Commissions	Child Support
Alimony	Workers' Compensation
Net earnings from self employment	Pensions
Unemployment Compensation	Annuities
Veteran's Benefits	Help from relatives and others
Social Security cash benefits	Gambling/Lottery winnings

At the each enrollment and subsequent annual recertifications, the patient must document all household income for the patient and his/her spouse. Acceptable documentation could include most recent paycheck stubs; signed employer statements with name of employer, date, position, and phone number; Earnings Statement from the Social Security Administration; Social Security Award letters; Wages Statement from the Employment Security Commission; SSI; AFDC; Food Stamp letters; military benefits; retirement income; or other employment income. **Documentation of income must be included with the application** and will be retained in ADAP files. Proof of household income will also be required on the annual recertification forms and will be retained in ADAP files. **Household size** is defined as the patient, his/her spouse, and any dependent children residing in the household.

If a patient states that he/she has had zero or extremely low income coming into the household for more than a few months there needs to be a notation in the provider records as to how food, shelter, and utilities are being managed. This may be explained if the patient lives with someone rent-free, lives in a migrant camp, or uses a homeless shelter, and receives food stamps. Such situations may call for involving a case manager, if the patient does not have one.

Patients who claim no income will be required to go to the Employment Security Commission and get a current wage statement documenting no income. In the case of an individual who does not have legal status in the United States, an Income Statement for Undocumented Persons Living in SC form explaining the patient's support system and income must be attached. See Appendix.

1. Income Eligibility Limits

Income equal to or less than 300 percent of the current federal poverty guidelines is required for program eligibility in order to receive medications at no cost. **Please note:** A sliding fee scale based on current federal poverty guidelines will be used to determine other eligibility for patients who have income in excess of 300 percent. A copy of the current SC ADAP Sliding Fee Scale may be found in the appendices of this guideline and at <http://www.dhec.sc.gov/health/disease/stdhiv/adap.htm>. Poverty guidelines are revised annually; therefore it is important to make sure that current guidelines are used.

For SC ADAP eligibility purposes, household income is defined only as the patient's income and his/her spouse's income. There may be household combinations with other relatives or friends. A person living with a friend, who is providing only food and shelter, would be counted as a household of one. The only income considered would be that of the patient. In the case of a patient and his/her spouse with two children, the income of only the patient and his/her spouse would be counted for a household of four. Household size is defined as the patient, his/her spouse, and any dependent children residing in the household. The proof of household income for SC ADAP eligibility purposes must be included when making the determination.

2. Recently Discharged Hospital Patients

SC ADAP currently does not have a wait list. If the wait list is reinstated because of funding limitations, patients who have been hospitalized and are discharged from the hospital on antiretroviral drugs will be expedited into SC ADAP. This will be done so a patient will not have the drug regimen interrupted, even if he/she is unable to provide immediate documentation of income. Please note that the patient must currently be taking the drugs. He/she is permitted to enroll in the program based on self-declared income and given ten (10) workdays to provide documentation of income as specified in this guideline. Drugs are to be provided based on this self-declared income for the first month of eligibility. If the patient was not discharged on any drugs and is not currently taking any drugs of any type, then regular application requirements and time frames apply. It is the responsibility of the person completing the enrollment to check with the patient to determine if he/she was discharged from the hospital on any type of drug treatment.

3. Patients Who Lose Medicaid Benefits

A patient who loses Medicaid benefits may be able to enroll in the SC ADAP.

4. Patients with Health Insurance Coverage for Prescriptions

A patient with health insurance that covers SC ADAP drugs is not eligible to receive his/her drugs from Central Pharmacy, but may be enrolled in the SC ADAP Insurance Assistance Program to receive assistance with payment of copays, deductibles, and premiums. (See VIII. Insurance Assistance Program.) The financial and medical eligibility requirements for the Insurance Assistance Program are the same as for patients without insurance. Eligibility in the Insurance Continuation Program differs in that the financial requirements do not allow for a sliding fee scale and that there is a cap on liquid assets. A patient's household income must be equal to or less than 300% of the federal poverty guideline and must have less than \$10,000 in liquid assets (page 21) to qualify financially. A SC ADAP Insurance application will need to be completed in order to enroll in these programs.

In certain cases, if a patient has health insurance with **limited** pharmacy benefits, he/she may be eligible to receive their drugs from Central Pharmacy. This includes a patient who has a low financial cap on pharmaceutical benefits. The financial and medical eligibility requirements are the same as patients without insurance and a SC ADAP Central Pharmacy application will need to be completed in order to enroll.

5. Other Insurance or Pharmaceutical Benefits

To receive SC ADAP services, a patient must demonstrate ineligibility for Medicaid, Medicare, or any other program that reimburses for drugs. Before applying for SC ADAP benefits, every patient must be evaluated to ensure that ADAP is the payor of last resort.

If a patient appears to be Medicaid eligible, he/she **must** be referred for eligibility determination, and must follow through on the referral. A patient may be enrolled in SC ADAP during the referral and Medicaid application/eligibility determination process.

Once a SC ADAP patient is approved for Medicaid benefits, he/she is no longer eligible for this program and must be closed. The only exception to this policy is if a female patient is receiving Medicaid benefits for the purpose of family planning coverage only, then she is still eligible for the SC ADAP.

Medicaid eligible patient should have his/her prescriptions filled at a local pharmacy

Should a patient not follow through with the Medicaid application, his/her case manager should assist in resolving the situation. A patient who refuses to follow through with a Medicaid application, or who refuses to use Medicaid and/or private insurance pharmacy benefits is not eligible for SC ADAP.

Written proof of denial of Medicaid or ineligibility for Medicaid is required by ADAP. Documentation of ineligibility must be retained in provider files, and be available to ADAP for review upon request.

Dual Eligible and full Low Income Subsidy Medicare Part D drug benefit patients are not eligible for SC ADAP services and will be closed from the program. The SC ADAP will continue to assist patients eligible for the Medicare Part D prescription benefit with an income of between 135-550% of FPL.

C. Medical Eligibility Criteria:

1. Documentation of HIV Infection

A patient must have a documented HIV infection or AIDS diagnosis in order to be medically eligible for the program.

2. Initial Laboratory Reports

If antiretroviral drugs are to be prescribed, current U.S. Department of Health and Human Services/National Institutes of Health (DHHS/NIH) Guidelines should be followed with regard to obtaining viral load values and CD4 counts prior to initiation of treatment. It is expected that generally accepted treatment protocols would be followed. This is applicable to both public and private physicians. Any unusual practices or “off label” treatments need to be discussed with the SC ADAP pharmacists or SC ADAP Medical Consultant (see SC DHEC STD/HIV Division, AIDS Drug Assistance Program Procedures in the appendices).

3. ADAP Formulary

The formulary for the SC ADAP consists of all of the currently FDA approved antiretroviral medications, Hepatitis C medications, as well as other drugs deemed necessary for the treatment and quality of life of the

HIV patient (See appendix for the current list). This list includes antivirals, antifungals, drugs used in the treatment of mycobacterium avium complex (MAC), toxoplasmosis, CMV retinitis, PCP, and antidepressants. As a federally funded program, ADAP must closely monitor our expenditures to ensure budget compliance. Should funding become limited, ADAP may have to institute access restrictions. These restrictions could range from limiting the formulary, reduced financial eligibility criteria, and imposed cost sharing, to capping enrollment of new patients.

4. Ongoing Laboratory Reports

The SC ADAP recommends that a patient receive laboratory evaluations while undergoing treatment. These evaluations should be in accordance with the National Institutes of Health Guidelines. Baseline viral load and CD4 lab values should be obtained prior to the start of antiretroviral therapy (ART) and then twice a year thereafter.

Treatment guidelines are not intended to replace the judgment of a physician. The decision to prescribe certain treatments lies with the physician and the patient. However, it is expected that the current recommended protocols would be used for determining treatments. It is also expected that drug protocols will be in keeping with currently accepted practices and any guidelines set forth by the SC ADAP. Certain contraindicated drug combinations may not be dispensed without the approval of the SC ADAP medical consultant. If there are any questions, contact the SC ADAP.

Applications must be completed in their entirety before submission to SC ADAP. The patient and the case manager should complete the front of the application. The physician should complete the back of the application, to include checking medications being prescribed. The ideal treatment regimen for a patient is one in which the patient receives medications consistent with PHS guidelines.

If a patient chooses not to take HIV antiretroviral (ARV) medications, this should be documented in his/her chart. In October 2001, a revision to the ADAP guidelines eliminated the requirement for medical review when Opportunistic Infection related medications are ordered in the absence of HIV antiretroviral medications. See attached updated ADAP Application Medical Management Procedures.

For some patients, providers agree on or plan for a period of time when the patient does not take antiretrovirals. ADAP refers to this situation as **Med Hold**. The intent of **Med Hold** status is to allow the physician a short

time to get the patient ready to take antiretrovirals, or to allow the selection of a new medication regimen due to side effects or drug resistance. If the physician is planning an extended Med Hold (longer than six months), reasons for the extended delay of medication therapy will be required. Some patients may need to be closed and reapplied at a later date when they are ready to begin ARV medication therapy.

When patients are placed on Med Hold, Central Pharmacy will contact the physician's office twice a year or as staffing allows to determine the patient's status and if the patient has been keeping appointments and the date of the last appointment. Patients lost to follow-up will be closed; this can be counted as closed by Physician's request and will not count as a non-adherent incident against the patient. Med Hold is not a status to be used to save a non-adherent patient from closure.

Patients who are only receiving antidepressants will be reviewed after six months of utilization and continuation will be determined on a case-by-case basis by the ADAP medical consultant.

5. Coordination with Case Management Services

At every opportunity, SC ADAP services should be coordinated with case management services. The case manager should be involved in assisting the patient to enroll in SC ADAP and access other needed services.

There are two types of case managers indicated on the SC ADAP Application:

1) Referring Case Manager: The nurse or social worker that will serve as ADAP's point of contact and be responsible for actively monitoring the progress and medication adherence of the patient. The Referring Case Manager should be involved on a regular basis to assist the patient in remaining enrolled in the drug program and in applying for other benefits that might provide drug coverage, such as Medicaid. The case manager should also assist the patient in adhering to his/her drug regimens. When a patient fails to call for refills, the case manager and/or the medical care staff may be notified by ADAP staff. The SC ADAP staff, medical professionals, and the case manager should act as a team to support the patient in order to assure adherence to treatment and access to needed services.

2) Non-Referring Case Manager: A nurse or social worker that is only assisting in filling out the ADAP application for the patient and **will not be responsible for treatment adherence.** In such instances, the only signature required will be on the front of the application as a witness.

In most cases, the application will be forwarded to the nurse or social worker that will actively monitor the patient.

III. Enrollment and Ongoing Eligibility

A. Wait List

Currently, SC ADAP does not have a wait list. This wait list will be reinstated if necessary due to limited funding.

It is recommended that, whenever possible, a physician delay starting drugs until acceptance into the SC ADAP has been approved.

B. Initial Enrollment Procedures

This procedure is to be used for all applicants. For enrollment, an application is completed and sent to the SC ADAP. **SC DHEC requires submission of documentation of household income with each application.** Acceptable documentation could include most recent paycheck stubs; signed employer statements with name of employer, date, position, and phone number; Earnings Statement from the Social Security Administration; Social Security Award letters; Wages statement from the Employment Security Commission; SSI; AFDC; Food Stamp letters; military benefits; retirement income; or other employment income.

Note: For each application and annual recertification, a case manager, nurse, physician, or other unrelated person is never permitted to sign a patient's name, or sign in the place of the patient for any reason. A caretaker or spouse is not allowed to sign, unless the patient is completely physically incapacitated and cannot sign his/her name. There must be written justification for caretaker or spouse signatures in the patient's record. A court-appointed guardian may sign for an individual who has been adjudicated incompetent by a judge and a copy of the court order must be placed in the patient's file. Persons designated with Power of Attorney for Health Care may sign for an individual and a copy of the Power of Attorney must be placed in the patient's file.

C. Recertification

ADAP will require patients to recertify once a year. Central Pharmacy patients will recertify in their birth month while Insurance program clients (due to the program's smaller size) will recertify in the same month. **The recertification will include documentation of household income** and the most recent CD4 and viral load. Recertification forms should be returned within thirty days of receipt. The process of filling out recertification forms is the same as filling out initial applications with the exception of only needing one signature on the recertification form. The provider assisting in filling out the form should sign the

recertification form. **Patients who do not recertify annually will be removed from the SC ADAP after 90 days.** SC DHEC also requires submission of documentation of household income with each recertification. Acceptable documentation could include most recent paycheck stubs; signed employer statements with name of employer, date, position, and phone number; Earnings Statement from the Social Security Administration; Social Security Award letters; Wages statement from the Employment Security Commission; SSI; AFDC; Food Stamp letters; military benefits; retirement income; or other employment income.

In an attempt to assure that SC ADAP is the payer of last resort, ADAP staff matches client files with Medicaid files on an individual basis before each service to ensure that approved Medicaid patients can be removed from the active SC ADAP roster in a timely manner. In 2006, SC ADAP will begin back billing Medicaid for prescriptions dispensed to Medicaid eligible patients by Central Pharmacy.

D. Prescriptions

Prescriptions will be filled on a monthly basis with two refills. Program staff will review exceptions to this policy. New prescriptions from the physician need to be sent to SC ADAP every three months. ADAP Central Pharmacy requires the faxing of prescriptions versus calling them in as a quality management tool.

E. Drug Updates

Drug Updates are submitted when there is change in a patient's medication regimen in between recertifications. For example, a patient is started on a combination of three drugs at the time of enrollment or eligibility recertification. Two months later, one or more of the drugs is discontinued in order to substitute a different drug. Procedures for drug updates are as follows:

- Case managers or physicians' offices will submit new prescriptions to ADAP. When new prescriptions are submitted, information concerning discontinued medications and/or additions to therapy is needed in Central Pharmacy. If this information is not submitted, ADAP will call the physician.
- If a physician prescribes a sub-standard or off label therapy, ADAP may require periodic lab results in order for a patient to get drugs through ADAP. If this is a new patient, previous laboratory results, or a copy of published documentation of therapy (e.g. peer review journal article, abstract, or study that is ongoing) may be required.

F. Termination of Services

Termination of services from the SC ADAP may occur for a number of reasons:

- The patient has been determined eligible for Medicaid benefits;
- The patient's income rises to more than 550 percent of the current poverty level;
- The patient moves out of the state of South Carolina or cannot be located;
- The patient does not reside in the state of South Carolina;
- The patient goes to prison (see Section V. A. for clarification of status of pretrial detainees);
- The patient has a poor adherence record requiring adherence intervention on three separate occasions;
- The patient fails to request medications in any 90 day period, and/or is refusing to adhere to the medication regimen despite counseling and support or other assistance offered;
- It is discovered that the patient failed to report substantial income that made him/her ineligible at the time of application or subsequent to application;
- The patient fails to provide necessary proof of eligibility, i.e. does not submit recertification in a timely manner;
- The patient dies.

When a patient is terminated from the program, the date and reason for termination will be documented in the SC ADAP record.

G. Change of Address

For patients who move within the state, there are no changes in SC ADAP services. When a patient calls the SC ADAP, his/her address will be verified prior to any additional dialogue. This is important for verification that the person on the phone is the person enrolled in the program. Further verification such as date-of-birth or social security number may be required if deemed necessary to establish identification.

H. Non-Adherence/Failure to Request Medications

A patient who fails to request drugs within a 90-day period may be automatically terminated. If pharmacy records show that a patient has gone extended periods between refills, an adherence letter will be sent to the patient, physician, and case manager, if the patient has one. The letter states the date of non-adherence, and requests an explanation of non-adherence. A written reply to this letter must be sent to the SC ADAP. If a physician discontinues a patient's medications, the physician or case manager must inform the SC ADAP of the termination of medications, or the patient will be terminated from the program. The patient must keep medical appointments in order to remain enrolled in the program.

The SC ADAP Three-Chance Program is outlined below.

Chance 1 - After a client has been closed for non-compliance for the first time, he/she may reapply to the ADAP program at any time that he/she feels ready and able to stay adherent, but must first complete a two month “getting ready period.” During this time the client should receive additional adherence counseling from his/her case manager/provider.

Chance 2 – If a client has been closed a second time for non-compliance, the client can again reapply when he/she feels ready and able to stay adherent, but must first complete an additional three months of more intensive adherence counseling from his/her case manager/provider.

Chance 3 - If a client has been closed for non-compliance after a third activation on the program, any future reapplications would require a letter of appeal from the physician. The ADAP Pharmacists and the HIV Medical Consultant will review documentation of changes in the client’s life and ability to adhere to the medication regimen on a case-by-case basis. The intent is to allow patients who have experienced significant changes in lifestyle, resulting in an apparent increased capacity to adhere to a complex drug regimen, to be given an additional opportunity to demonstrate compliance. Physicians will be notified in writing of the final determination of application status.

IV. Records Documentation and Retention

A. SC ADAP Records

Applications and recertification forms, as well as copies of correspondence and prescriptions, will be maintained in SC ADAP files.

Records of any deceased patients will be retained for four years after the patient’s death, and reviewed by SC ADAP staff before being destroyed. Other patient records will be retained for 13 years after the last time the patient receives services from SC ADAP and until no longer needed for reference, and then reviewed by SC ADAP staff before being archived or destroyed.

B. Provider Records

Documentation of HIV infection diagnosis, CD4 counts, viral loads, documentation of income, Medicaid eligibility review and denial, patient information forms, and copies of each signed application must remain with the patient’s medical and/or case management record. Written proof of denial of Medicaid or ineligibility for Medicaid is required by ADAP and must be retained in provider records. Documentation of ineligibility must be retained in provider files, and be available to ADAP for review upon request. The SC ADAP may conduct yearly random samples of current ADAP patients (both Central Pharmacy

and Insurance Program) from both consortia and private providers, to ensure that complete documentation meeting program guidelines is in place. SC DHEC requires providers to retain records for six years after the end of the contract period, and records shall be available for audit and inspection at any time such audit is deemed necessary by SC DHEC. If an audit has begun but is not completed at the end of the six-year period, or if audit findings have not been resolved at the end of the six-year period, the records shall be retained until resolution of the audit findings.

V. City and County Jails, Department of Corrections

Once an individual is incarcerated, the jail or prison is legally responsible for that individual's room, board, and medical care. Individuals who are incarcerated are residing in institutions, and are not eligible for SC ADAP services. When an individual is incarcerated, he/she must be terminated from the program. This provision applies to all city and county jails, state and federal prisons. One exception to this policy exists based on July 2001 revisions to the CARE Act that supports the use of CARE Act funds for transitional social support and primary care services for incarcerated persons for a brief period. The SC ADAP issued a letter on April 10, 2002 informing the South Carolina Association of Counties that, effective immediately, the SC ADAP will be able to supply medication to pretrial detainees who are currently receiving their HIV medication through the SC ADAP. This will be dependent upon the availability of federal funding for this program.

A. City and County Jails

Any patient incarcerated in a city or county jail must be terminated immediately from the SC ADAP. The exception to this policy described above allows for pretrial detainees who are currently receiving their HIV medication through the SC ADAP and, are in good standing with the program, to receive medications for a period of up to 180 days. If other funding for medical treatment becomes available to county/city detention facilities, it will be the responsibility of the facility in which the detainee is being held to notify SC ADAP immediately. If the SC ADAP provides medications to pretrial detainees, no additional charges are to be assessed by local jails for dispensing these medications. A detainee would take any medications with him upon release. Also, SC ADAP must be notified prior to release of the inmate in order to adequately provide for discharge planning and transition to another care provider. This policy will be dependent upon the availability of federal funding for this program.

It is permissible for a Ryan White case manager to do "transitional" case management with an inmate to be released within 30 days.

B. Department of Corrections

Any patient incarcerated in a Department of Corrections (DOC) correctional facility, including those under contract to any state or municipal entity, must be terminated immediately from the SC ADAP. It is permissible for a Ryan White case manager to do “transitional” case management with an inmate about to be released within 30 days.

The SC DHEC and DOC have developed a protocol that provides assistance for HIV infected patients on drug regimens who are discharged from DOC facilities and are unable to procure drugs from other resources. The protocol is as follows:

- The patient must be on an HIV medication regimen prior to release from the DOC.
- The DOC initiates arrangements at least 30 days prior to release of the patient.
- The DOC discharge planner will contact the local consortium to facilitate the application being filled out and prescriptions obtained for patient.
- The DOC is responsible for making arrangements for a 30-day supply of drugs to be given to the prisoner at discharge.
- The patient is responsible for making contact with the local consortium to complete enrollment into SC ADAP and obtain necessary drugs within 30 days of discharge.
- If the patient does not follow through by contacting the consortium within 30 days of discharge, he/she will be subject to the same enrollment and wait list (if applicable) procedures as any other individual applying for services.
- Eligibility recertification and all other SC ADAP policies and procedures apply to these patients.
- Payor of last resort applies to these patients. Documentation of application to Medicaid and follow through must be retained in files.

C. Probation and Parole

Persons who are on probation or parole are eligible for SC ADAP services since they are living in the community. These individuals are not in the care or custody of a jail or prison system, although they may be reporting to a parole or probation officer. Persons who are on House Arrest will need to be dealt with on a case-by-case basis.

VI. Out of State Physicians and Prescriptions

Prescribing physicians, with one exception, are to be licensed to practice in the state of South Carolina. A patient who sees physicians in bordering states of North Carolina and Georgia may continue to obtain medications from SC ADAP as long as he/she meets the SC ADAP eligibility criteria.

VII. Grievance Procedures

Types of Grievances

- A. Consumers may express their dissatisfaction with the SC ADAP.
- B. Providers/agencies may express dissatisfaction with the SC ADAP.

If a consumer, provider or agency wishes to address a concern with a SC ADAP policy, the following procedure is recommended:

- The consumer, provider or agency is requested to address the concern immediately with SC ADAP staff or the Ryan White Title II Program Manager.
- Staff will respond to or address the concerns expressed in a timely manner either verbally or in writing.
- In the event that the staff cannot resolve the issue, he/she will document and forward the concern to his/her supervisor.
- If necessary, the Supervisor will review the concern with the STD/HIV Division Director and management team, determine the appropriate response and communicate that response to the staff.

VIII. Insurance Assistance Program

At the each enrollment and subsequent recertifications, the patient must include documentation all household income for the patient and his/her spouse. Acceptable documentation could include most recent paycheck stubs; signed employer statements with name of employer, date, position, and phone number; Earnings Statement from the Social Security Administration; Social Security Award letters; Wages Statement from the Employment Security Commission; SSI; AFDC; Food Stamp letters; military benefits; retirement income; or other employment income. Documentation of income will be retained in ADAP files.

If a patient states that he/she has had zero or extremely low income coming into the household for more than a few months there needs to be notation in the provider records as to how food, shelter, and utilities are being managed. This may be explained if the patient lives with someone rent-free, lives in a migrant camp or uses a homeless shelter, and receives food stamps. Such situations may call for involving a case manager, if the patient does not have one.

Patients who claim no income will be required to go to the Employment Security Commission and get current wages statements documenting no income. There can be no

exceptions to this policy since federal regulations require the Program to show that we are the payor of last resort and that income criteria are being met.

A. Insurance Copay

Purpose: To pay out of pocket expenses, to include copays and deductibles, for patients with health insurance coverage for prescriptions.

1. Eligibility

- a. The financial and medical eligibility requirements are the same as those without insurance.
- b. Applications must be made in writing on a form prescribed by the SC ADAP dated 04/2006. SC ADAP Insurance Applications may be obtained from the ADAP, one of the local providers, or through the STD/HIV Division's website at: <http://www.dhec.sc.gov/health/disease/stdhiv/adap.htm>. Attach a copy of the front and back of the insurance card to the application.

2. Time Frames

In general, all applications will be reviewed within 30 days of receipt. Approved applications will usually be activated within 60 to 120 days of receipt. Once a decision is made, patients, physicians, and case managers should receive written or electronic notification within 10-15 working days of final determination of application status. Any changes to the application once submitted, will result in additional processing time.

Patients must make arrangements to get their medications through other means until their SC ADAP application has been activated and they or their case manager receive an acceptance letter.

3. Formulary

Reimbursement can only be made for medications on the SC ADAP Formulary (see attached). This is the same formulary that the SC ADAP Central Pharmacy uses with the exception that the Insurance program will reimburse for both generic and brand name drugs on the formulary. Due to the relatively small copay amount compared to purchase price, no additional applications are necessary to prescribe Fuzeon or Hepatitis C medications for ADAP Insurance Copay patients. The Insurance program will rely on the prescribing physician's approval.

If after activation it is determined that the patient's drug formulary is not

equivalent to the SC ADAP formulary, the patient will be closed and transferred to Central Pharmacy. Should this happen, the patient, case manager, and/or physician will be notified. Reimbursements will not be paid after the effective date of a closure and a notification of closure has been sent, either verbally or in writing.

4. Where to Get Medications

- a. For new patients not enrolling through their local consortium: Insurance patients cannot get their medications from the SC ADAP Central Pharmacy. All new patients will be enrolled with a contracted mail order pharmacy, unless the insurance policy specifies that the patient must use a network pharmacy.
- b. For patients enrolling through their local consortium: Providers may make payment arrangements for medications then bill the SC ADAP for reimbursement once patient is activated in the Insurance Assistance Program.
- c. Patients should not be sent to any pharmacy to pick up medication before the SC ADAP has arranged for coverage. To do so may jeopardize reimbursement of that medication. Medications picked up prior to the acceptance date of the SC ADAP application cannot be reimbursed.
- d. Patients cannot be reimbursed directly for co-pays or deductibles under any circumstances.

5. Reimbursement Requests

Insurance reimbursement requests will be processed within 30 days of receipt, depending on staff availability. From that point, it will take an additional 2 - 3 weeks to receive a check.

6. Losing/Getting Insurance

- a. If a patient loses his/her insurance, the SC ADAP must be notified immediately. The patient may be eligible to receive his/her medications from the SC ADAP Central Pharmacy.
- b. If a patient is currently receiving his/her medication from the SC ADAP Central Pharmacy and becomes eligible for insurance, the SC ADAP must be notified immediately to arrange for insurance reimbursement coverage.

B. Insurance Continuation

Purpose: To pay insurance/COBRA premiums for patients at risk of losing insurance due to the inability to afford payments or for losing job/insurance benefits. Patients must currently be on or starting ARV therapy upon ADAP activation. Documentation of the premium amount must be submitted with the application.

The SC ADAP must demonstrate overall cost effectiveness of the program. For instance, the cost of paying premiums for patients must overall be less than the cost of medications to Central Pharmacy. Also, the patient's insurance policy drug formulary must be equivalent to the SC ADAP Formulary.

1. Eligibility Process

a. Applications

- (1) Applications must be submitted on the SC ADAP Insurance Application dated 04/2006. Applications may be obtained from the SC ADAP, one of the local providers, or the STD/HIV Division website at <http://www.dhec.sc.gov/health/disease/stdhiv/adap.htm> Documentation of the premium amount must be submitted with the application.
- (2) Attach copies of the front and back of the patient's insurance card, insurance policy (if possible), and the drug formulary or verification of the SC ADAP Formulary. *Applications cannot be processed without verification of the drug formulary.*
- (3) If the insurance policy drug formulary cannot be obtained, (1) ask a local pharmacy to run the medications being prescribed from the SC ADAP Drug Formulary that the patient will be on. If those medications are allowed, attach documentation to the application; (2) if the patient is currently on medications, get the current pharmacy to run a Pharmacist Statement showing eligibility and attach documentation to the application.

b. Beginning and Ending Dates

- (1) **Assistance begins on the date the application is activated by ADAP. ADAP coverage will begin on the**

activation date. ADAP coverage will no longer begin on the first day of eligibility of the insurance policy.

- (2) Assistance is discontinued on the last day of the month in which eligibility ends.

c. Time Frames

The SC ADAP will process the completed application generally within 30-45 days of receipt. Longer periods may occur depending on workload and follow up required to obtain necessary application information.

d. Approval/Denial

Once a decision is made, patients, physicians, and case managers should receive written or electronic notification within 10-15 working days of final determination of application status. Any changes to the application once submitted, will result in additional processing time. **Only those applications that appear to be cost effective and have formularies equivalent to the SC ADAP formulary will be approved.**

If after activation it is determined that the patient's drug formulary is not equivalent to the SC ADAP formulary, the patient will be closed and transferred to Central Pharmacy. Should this happen, the patient, case manager, and/or physician will be notified. Reimbursements will not be paid after the effective date of a closure and a notification of closure has been sent, either verbally or in writing.

e. Certification Period

Certification continues until such a time, as the individual is found ineligible through periodic review of the recertification form or other eligibility evaluation.

2. Eligibility Requirements

The individual must furnish necessary information to determine eligibility at the time of initial application and at the times of periodic review of eligibility.

a. Criteria

- (1) The individual must be diagnosed by a physician as having HIV disease and must currently be on antiretroviral therapy or must start antiretroviral therapy upon ADAP activation.
- (2) The individual must be covered by health insurance (group or individual) before becoming eligible for this program.
- (3) An individual whose medical bills for treatment of HIV disease affect his financial ability to pay his/her individual health insurance premiums may apply for this program.
- (4) The program pays insurance premiums on behalf of an eligible individual only for as long as the individual qualifies for insurance coverage (i.e., COBRA or individual conversion coverage). This program is for patients with health insurance only; it does not pay for life, dental, vision, or other related insurance.
- (5) If an individual has third party funding as an interim to final medical disability determination (i.e., Social Security Disability), then that individual may apply for the program during the medical disability determination period.
- (6) Patients cannot be reimbursed directly for premiums under any circumstances.

b. Residency

Must be a resident of South Carolina.

c. Income Assets

- (1) The income standard is an amount equal to or less than 300% of the federal poverty level for the appropriate family size. The income standard will be reviewed on an annual basis.
- (2) There is no sliding fee scale. If the household income exceeds 300% of the federal poverty level, this program cannot pay for his/her health insurance.
- (3) The individual or couple must have less than \$10,000 in counted assets. Assets include only the following liquid assets:

Cash/Savings Stocks/Bonds

Mutual Funds Severance pay

An asset owned jointly by the individual or couple and another person is considered as belonging entirely to the individual or couple unless proven otherwise.

3. Standards of Assistance:

a. Standard of Assistance for Eligibility

- (1) The income standard is equal to or less than 300% of the federal poverty level for the appropriate family size.
- (2) If the patient's physician orders a medication hold, the SC ADAP medical consultant, on a case-by-case basis, will evaluate continuing eligibility.
- (3) If the patient voluntarily stops taking medications, he/she will be dropped from the program and the responsibility for making premium payments will return to the patient.

b. Standard of Assistance for Benefit Amount

- (1) The standard of assistance is equal to the premium that would be charged to an individual at the same level as immediately prior to the continuation.
- (2) **If the individual's medical insurance premium includes an amount for family coverage, the SC ADAP pays only that portion covering the individual.**

4. Verification:

a. Eligibility Requirements

- (1) Under group or individual insurance coverage, the individual must verify that he/she is HIV infected.
- (2) The individual must verify that he/she is eligible for continuation of health insurance coverage.

b. Assets

The individual must verify the value of counted assets, which he/she, or couple, if any, own. The patient's signature on the SC ADAP Application serves to verify this information.

c. Standards of Assistance

- (1) The individual must verify the amount of the premium that he/she is required to pay for continuation of health coverage.
- (2) If the insurance cost includes an amount for dependents, the individual must verify the amount that is required for continuation of insurance for the individual only.

d. Income Eligibility

- (1) The individual must verify the gross income that he/she, or household, if appropriate, has or expects to have during the certification period. **Documentation of income must be must be provided to ADAP at every application and recertification.**
- (2) For SC ADAP eligibility purposes, household income is defined only as the patient and the patient's spouse.

In order for the SC ADAP to approve payment of insurance premiums, the insurance policy must be reviewed and found that the insurance policy formulary is at least as comprehensive as the SC ADAP Formulary. Payments for insurance premiums must be less than the SC ADAP cost of prescription drugs in the aggregate.

C. Billing Procedures for the Insurance Assistance Program

1. Insurance Copay Patients

a. Reimburse Consortium (as selected on the SC ADAP Insurance Application)

- (1) After a patient has been approved for the Insurance Copay Program, ADAP may contact the agency making the copay payments to confirm billing arrangements.
- (2) An acceptance letter will be mailed/e-mailed to the Consortium only.

- (3) The agency making the copay payments can then invoice ADAP for reimbursement. The billing start date is indicated in the acceptance letter.
 - (a) Reimbursements can only be made for medications on the SC ADAP Formulary.
 - (b) Required billing information includes: patient name and SSN, date of service, drug name and strength, number of days prescribed, and amount of copay.
 - (c) Billing Requests: A separate billing statement is required on each patient. It is not necessary to send a separate invoice or to include the actual prescription tickets. *Documentation of eligible charges must be retained in local consortium files.*
 - (d) ADAP should be billed on a monthly basis.
- (4) Reimbursement requests will be processed within 30 days of receipt, depending on staff availability. It will then take an additional 2-3 weeks to receive a check. *Please note that the state does not pay late fees, interest, or penalties on overdue accounts.*

b. Reimburse Pharmacy (as selected on the SC ADAP Insurance Application)

- (1) After a patient has been approved for the Insurance Copay Program, ADAP will work with the patient to arrange for coverage. Once ADAP has a copy of the Pharmacy Enrollment form, the front and back of the insurance card, Patient Agreement form, and a Release of Information form (when appropriate), the selected pharmacy will be contacted to arrange for billing. *Billing arrangements cannot be made without these documents.*
- (2) Once arrangements have been made for a pharmacy to bill ADAP for the patient's copay and deductible, ADAP will give the pharmacy the patient's demographic information over the telephone, to include date of birth and social security number. The patient's acceptance letter, a copy of the insurance card, and the Patient Agreement form will then be faxed to the pharmacy. The pharmacy billing start date is the date of acceptance into ADAP, as is indicated by

the date of the acceptance letter.

- (3) ADAP will then notify the patient, either by mail or by phone, of the name of the pharmacy and the pharmacy contact information. The patient will be instructed to contact his/her doctor for prescriptions and then to contact the pharmacy to make sure they have everything they need.
- (4) Once the pharmacy has received prescriptions for the patient and it has been determined that there is no problem with the insurance, the pharmacy can fill those prescriptions and bill the insurance company their portion and ADAP for the patient's portion. *ADAP can only be billed after insurance has paid their portion or the insurance portion has been determined.*
 - (a) Reimbursements can only be made for medications on the SC ADAP Formulary.
 - (b) Required billing information includes: patient name, date of service, prescription number, drug name and strength, NDC code, quantity prescribed, number of days prescribed, copay amount, and the pharmacy name, address and phone #.
 - (c) Billing Requests: A separate Pharmacist Statement is required on each patient. It will not be necessary to send a separate invoice or to include the actual prescription tickets.
 - (d) If there is a problem or question about the patient's insurance, prescriptions should not be filled without contacting ADAP. Doing so may jeopardize reimbursement of those medications.
 - (e) ADAP should be billed on a monthly basis.
- (5) Reimbursement requests will be processed within 30 days of receipt, depending on staff availability. It will then take an additional 2-3 weeks to receive a check. *Please note that the state does not pay late fees, interest, or penalties on overdue accounts.*

2. Insurance Continuation Patients

a. Reimbursement of Copay

Reimbursement of copay for Insurance Continuation patients will be the same as outlined in Section 1 above.

b. Reimbursement of Premium to Consortium

- (1) After a patient has been approved for the Insurance Continuation Program, ADAP may contact the agency making the premium payments to confirm billing arrangements.
- (2) An acceptance letter will be mailed/e-mailed to the Consortium only.
- (3) The agency making premium payments can then invoice ADAP for reimbursement. The billing start date is the date of acceptance into ADAP, as is indicated in the acceptance letter or the first day of the month in which the application is received.
- (4) Two invoices per patient are required:
 - (a) The first invoice must include the patient's name, dates of service, payment amount, total amount being billed, and the contract number. The SC ADAP will only reimburse for the patient's medical health insurance. Proof of premium amount(s) must be attached to the first bill and must indicate health insurance for the patient only. Anytime there is a change in the monthly premium amount, documentation of the new amount must be submitted before the new amount can be processed.
 - (b) The second invoice should not contain the patient's name or any other identifying information. All other information on the invoices should be the same.

c. Reimbursement of Premium through 3rd Party Billing

The following Providers must arrange reimbursement of premium payments through 3rd party billing: Midlands and Trident.

- (1) After a patient has been approved for the Insurance Continuation Program, the patient will receive an acceptance letter instructing him/her to call SC ADAP to arrange for coverage. At this time, ADAP will confirm all necessary information is in the patient's file and, if not, will request necessary information from the patient before proceeding with payment arrangements.
- (2) Once the required information is in the patient file, ADAP will contact the pre-arranged 3rd party billing agency, giving them the patient name, date of birth, and social security number. ADAP will then fax the appropriate insurance information along with an Insurance Premium Notification form to the billing agency. The Insurance Premium Notification form outlines pertinent patient information, such as name, address, monthly premium amount, payment due date, and special notes. The patient's Provider will also receive a copy of the acceptance letter and a copy of the Insurance Notification form.
- (3) ADAP will then contact the patient instructing him/her to contact the billing agency to verify they have all the necessary insurance information and to make final payment arrangements. For example, will the patient mail or fax a monthly statement for payment or will the billing agency automatically make the payment? This information must be worked out between the patient and the billing agency.
- (4) The 3rd party billing agency making premium payments on behalf of the Consortium can then invoice the Consortium who will then invoice SC ADAP for reimbursement.
- (5) Two invoices per patient are required:
 - (a) The first invoice should contain the patient's name, dates of service, payment amount, and the total amount being billed. The SC ADAP will only reimburse for the patient's medical health insurance. Proof of premium amount(s) must be attached to the first bill and must indicate health insurance for the patient only. Anytime there is a change in the monthly premium amount, documentation of the new amount must be submitted before the new amount can be processed.

- (b) The second invoice should not contain the patient's name or any other identifying information. All other information on the invoices should be the same.
- (6) Reimbursement requests will be processed within 30 days of receipt, depending on staff availability. It will then take an additional 2–3 weeks to receive a check. *Please note that the state does not pay late fees, interest, or penalties on overdue accounts.*

Mail all reimbursement requests to:

Matthew Williams
3rd Floor, Mills/Jarrett
Box 101106
Columbia, SC 29211
Phone: 803-898-4268
Secure Fax: 803-898-7683

IX. Security and Confidentiality

A. Security

1. The physical location of SC ADAP pharmacy and insurance program offices will be maintained in a secure manner. Staff will keep doors secure and all staff will be oriented to appropriate security when answering phones, etc.
2. Pharmacy and insurance program client files must be maintained in a secure manner. All medications must be maintained in a secure manner within the SC ADAP pharmacy location. Visitors to the SC ADAP pharmacy must remain in the public area at all times, unless escorted by a staff member to a location within the office that is clear of confidential files, records, or information.
3. SC ADAP staff matches client files against Medicaid files on an individual basis before each service to ensure that approved Medicaid patients can be removed from the active SC ADAP roster in a timely manner. Dates of birth and Social Security Numbers are used to do the match. Security must be ensured during this process.

B. Confidentiality

1. All agency confidentiality requirements for patient record information must be followed. All staff must be oriented to appropriate confidentiality precautions when answering phones, talking to clients or other staff, etc. Each staff member must sign a confidentiality statement. All staff must use discretion and should not discuss sensitive office issues, records or patient cases with anyone other than those involved in SC ADAP. Any known or suspected breaches of confidentiality will be immediately documented and brought to the attention of the employee's immediate supervisor. The Division Director will initiate and direct an appropriate course of action. HIV patient information may only be released to outside persons or agency representatives when the patient signs a properly completed authorization form.
2. Computers must be password protected. The *Provide* database will be used in all electronic communications when clients are being referred to since the transmission is encrypted and thus secure (reference the Security Summary for Provide Users). Faxes containing patient identifying information may be received at both Central Pharmacy and the Insurance Program, since secure fax machines are available. Internal and external documents must not contain the words HIV and/or AIDS except when necessary. Information with patient names and/or any other identifying information that is no longer needed must be shredded.
3. All statistical data released by the SC ADAP must be carefully scrutinized to be sure that no individuals can be identified. The Program Director will designate staff authorized to release statistical and other general information; persons without such authorization must refer queries to an authorized individual.